

Presentation

to

**Office of Management and Budget
Office of Information and Regulatory Affairs**

by

**Chris Hughes
Proprietor, Fat Cat Vapor Shop LLC**

**Representing
Pennsylvania Smoke
Free Alternatives Trade Association
(PA SFATA)**

December 2, 2015

12/2/2015

My name is Chris Hughes, and I own Fat Cat Vapor Shop LLC, in Montoursville, PA. I am also the President of the Pennsylvania Chapter of the Smoke Free Alternatives Trade Association (SFATA).

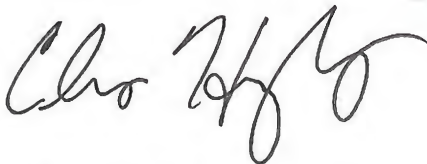
I smoked cigarettes for over 30 years, until being introduced to vapor products by a friend in September of 2011. After initiating with vapor products, I continued to smoke, though my use of cigarettes was greatly diminished. I went from smoking a pack and a half of cigarettes per day, to 2 or 3 cigarettes per day. This continued until early Oct of 2014. I have been completely smoke free since then.

Because of my very positive experience with these products, I decided to open a business offering vapor products to other adult smokers. After a year and a half of planning, Fat Cat Vapor Shop opened for business on 12/13/2015. Since that time, the business has continued to grow, and I feel our business has had a significant impact on smoking rates in our small town, something I take great personal pride in. Also since opening, I would estimate that we have had at least 75 to 100 new customers come in and tell us either they were sent specifically to our shop by their family doctor, or that switching to vapor products was suggested to them by their family doctor. I would add that we count a large number of RN's and LPN's, at least one Physician's' Assistant, and various people that work in other areas of the healthcare industry, as regular customers.

In my capacity as PA SFATA President, I donate a great deal of time to educating elected officials, and other government officials, and lobbying to preserve access to these products to adult smokers. Our chapter also has been working hard to advance a ban on the sale of vapor products to minors in PA. We hope that will be instituted in the next few months.

I want to thank you for taking time to meet with me to discuss the proposed FDA Deeming Regulation, its possible impacts on small vapor products businesses, and how it could affect access to reduced harm products to millions of American smokers.

Sincerely

A handwritten signature in black ink, appearing to read "Chris Hughes", written in a cursive style.

Chris Hughes
Owner- Fat Cat Vapor Shop LLC
President PA SFATA

Fat Cat Vapor Shop - 11/29/2015

2014-11-29 to 2015-11-29	ID
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ID	Subtotal	Discounts	Tax	Total	Cost	Profit	Margin	Date	Customer
29805	\$55.00	\$0.00	\$3.30	\$58.30	\$24.80	\$30.20	54.91%	11/29/2014	Pam Oneill

Subtotal	\$661,391.26	Taxed	\$655,697.73	Cost	\$300,245.19
Discounts	\$5,546.10	Not Taxed	\$148.20	Profit	\$355,599.97
Tax	\$39,346.61			Margin	54.22%
Total w/ Tax	\$695,191.77				

Electronic Cigarette Use Among Adults: United States, 2014

Charlotte A. Schoenborn, M.P.H.; and Renee M. Gindi, Ph.D.

Key findings

Data from the National Health Interview Survey

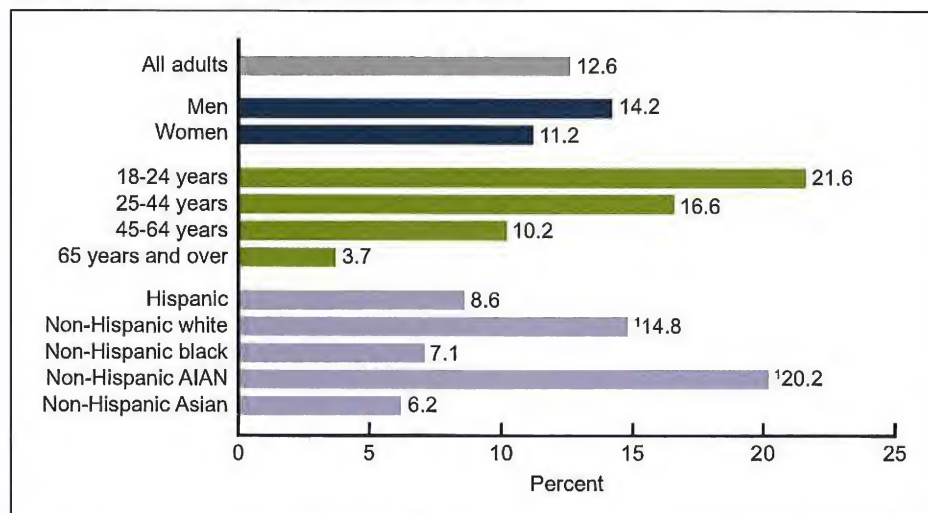
- In 2014, 12.6% of adults had ever tried an e-cigarette even one time, with use differing by sex, age, and race and Hispanic or Latino origin.
- About 3.7% of adults currently used e-cigarettes, with use differing by age and race and Hispanic or Latino origin.
- Current cigarette smokers and former smokers who quit smoking within the past year were more likely to use e-cigarettes than former smokers who quit smoking more than 1 year ago and those who had never smoked.
- Among current cigarette smokers who had tried to quit smoking in the past year, more than one-half had ever tried an e-cigarette and 20.3% were current e-cigarette users.
- Among adults who had never smoked cigarettes, 3.2% had ever tried an e-cigarette. Ever having used an e-cigarette was highest among never smokers aged 18–24 (9.7%) and declined with age.

Electronic cigarettes (e-cigarettes) are battery-powered products that typically deliver nicotine in the form of an aerosol (1). E-cigarettes have been marketed as both a smoking cessation tool and an alternative to conventional cigarettes (2). Results from several studies suggest recent rapid increases in e-cigarette use (3–7). In light of ongoing declines in conventional cigarette smoking prevalence (8), it is important to understand the extent to which e-cigarettes are being used among U.S. adults, both overall and by conventional cigarette smoking status. This report provides the first estimates of e-cigarette use among U.S. adults from a nationally representative household interview survey, by selected demographic and cigarette smoking characteristics.

Keywords: *electronic nicotine delivery system (ENDS), e-cigarettes, National Health Interview Survey*

In 2014, 12.6% of adults had ever tried an e-cigarette even one time in their lifetimes, with use differing by sex, age, and race and Hispanic or Latino origin.

Figure 1. Percentage of adults who had ever tried an e-cigarette in their lifetime, by sex, age, and race and Hispanic or Latino origin: United States, 2014



*Significantly different from Hispanic, non-Hispanic black, and non-Hispanic Asian subgroups.

NOTES: AIAN is American Indian or Alaska Native. Within sex and age groups, all subgroups are significantly different from each other. There is a significant linear trend by age group.

SOURCE: CDC/NCHS, National Health Interview Survey, 2014.

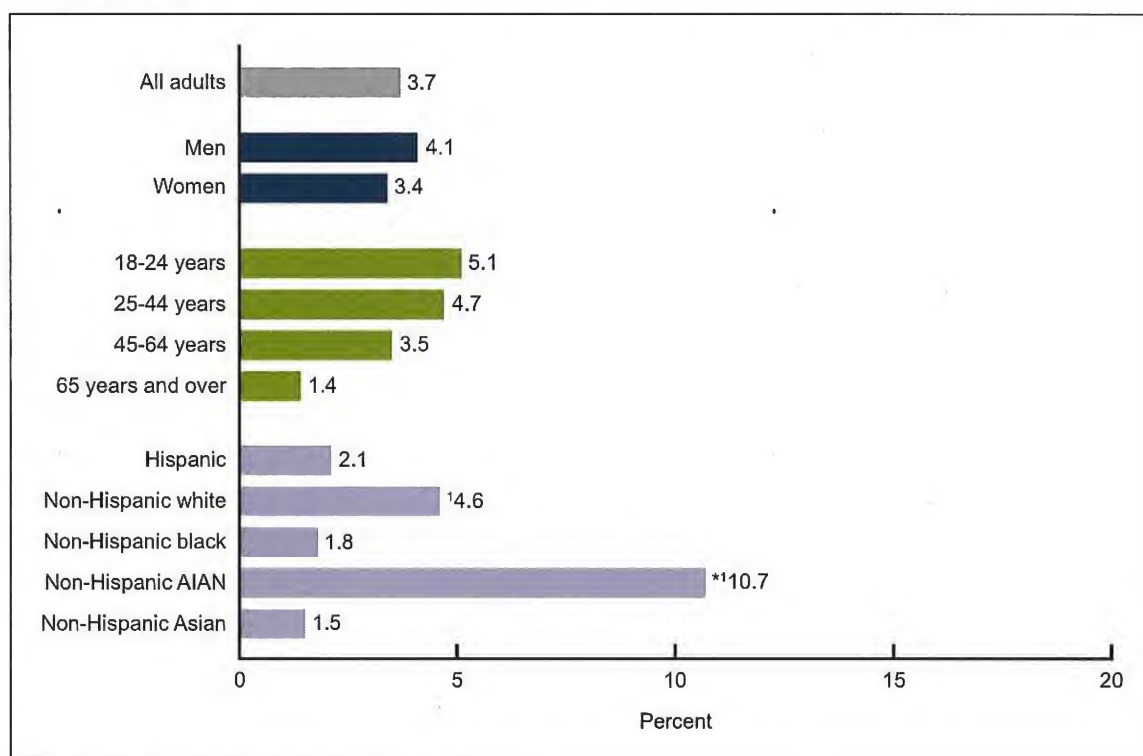


- Men were more likely than women to have ever tried an e-cigarette (Figure 1).
- More than 20% of adults aged 18–24 had ever tried an e-cigarette, with use declining steadily as age increased.
- Non-Hispanic American Indian or Alaska Native (AIAN) adults (20.2%) and non-Hispanic white adults (14.8%) were more likely than Hispanic (8.6%), non-Hispanic black (7.1 %), and non-Hispanic Asian (6.2%) adults to have ever tried an e-cigarette.

About 3.7% of adults currently used e-cigarettes every day or some days, with use differing by age and race and Hispanic or Latino origin.

- Current use of e-cigarettes was about the same for men and women (Figure 2).
- Current e-cigarette use was higher among non-Hispanic AIAN adults (10.7%) and non-Hispanic white adults (4.6%) than among Hispanic (2.1%), non-Hispanic black (1.8%), and non-Hispanic Asian (1.5%) adults.

Figure 2. Percentage of adults who currently use e-cigarettes, by sex, age, and race and Hispanic or Latino origin: United States, 2014



* Estimate has a relative standard error greater than 30% but less than 50% and does not meet standards of reliability or precision. The 95% confidence interval is 5.3–20.4.

*Significantly different from Hispanic, non-Hispanic black, and non-Hispanic Asian subgroups.

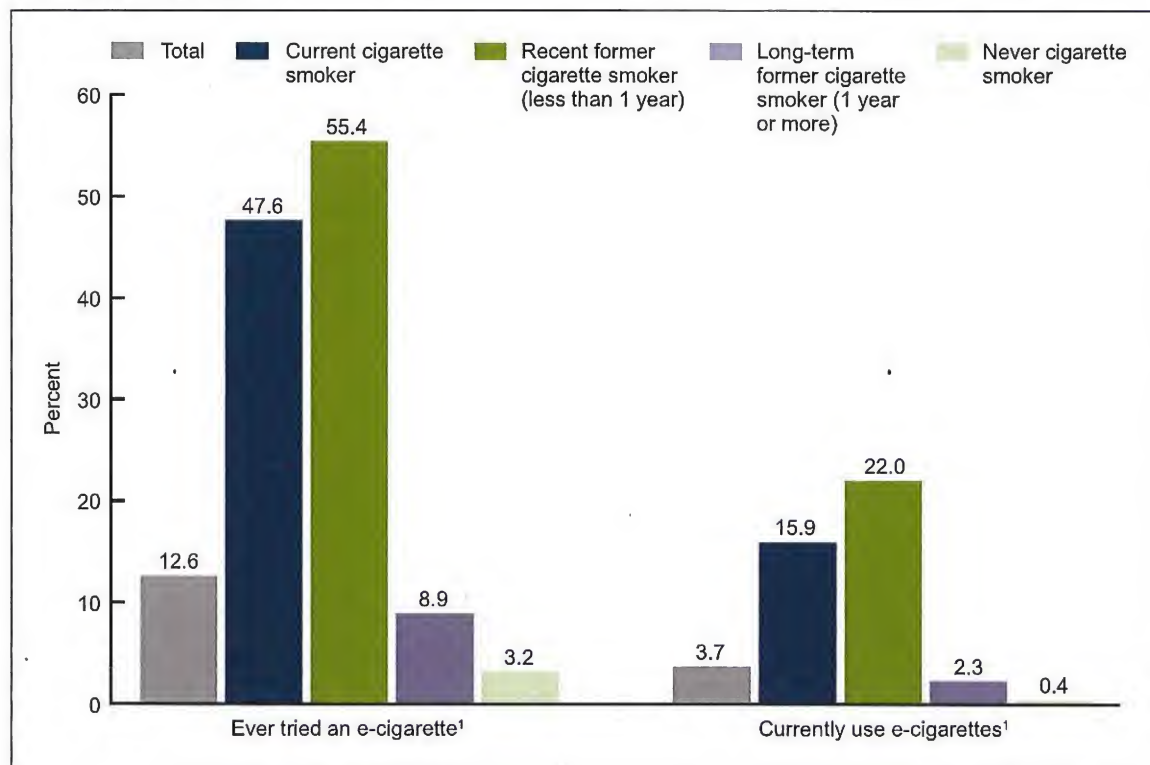
NOTE: AIAN is American Indian or Alaska Native.

SOURCE: CDC/NCHS, National Health Interview Survey, 2014.

Current cigarette smokers and recent former smokers (quit smoking within the past year) were more likely to use e-cigarettes than long-term former smokers (quit smoking more than 1 year ago) and adults who had never smoked.

- Almost one-half of current cigarette smokers (47.6%) and more than one-half of recent former cigarette smokers (55.4%) had ever tried an e-cigarette, compared with 8.9% of long-term former smokers and 3.2% of adults who had never smoked cigarettes (Figure 3).
- About one in six current cigarette smokers (15.9%) and nearly one in four recent former cigarette smokers (22.0%) currently used e-cigarettes, compared with 2.3% of long-term former cigarette smokers and 0.4% of adults who had never smoked cigarettes.

Figure 3. Percentage of adults who had ever tried and percentage who currently use e-cigarettes, by cigarette smoking status: United States, 2014



¹Percentages were significantly different across all smoking status groups.

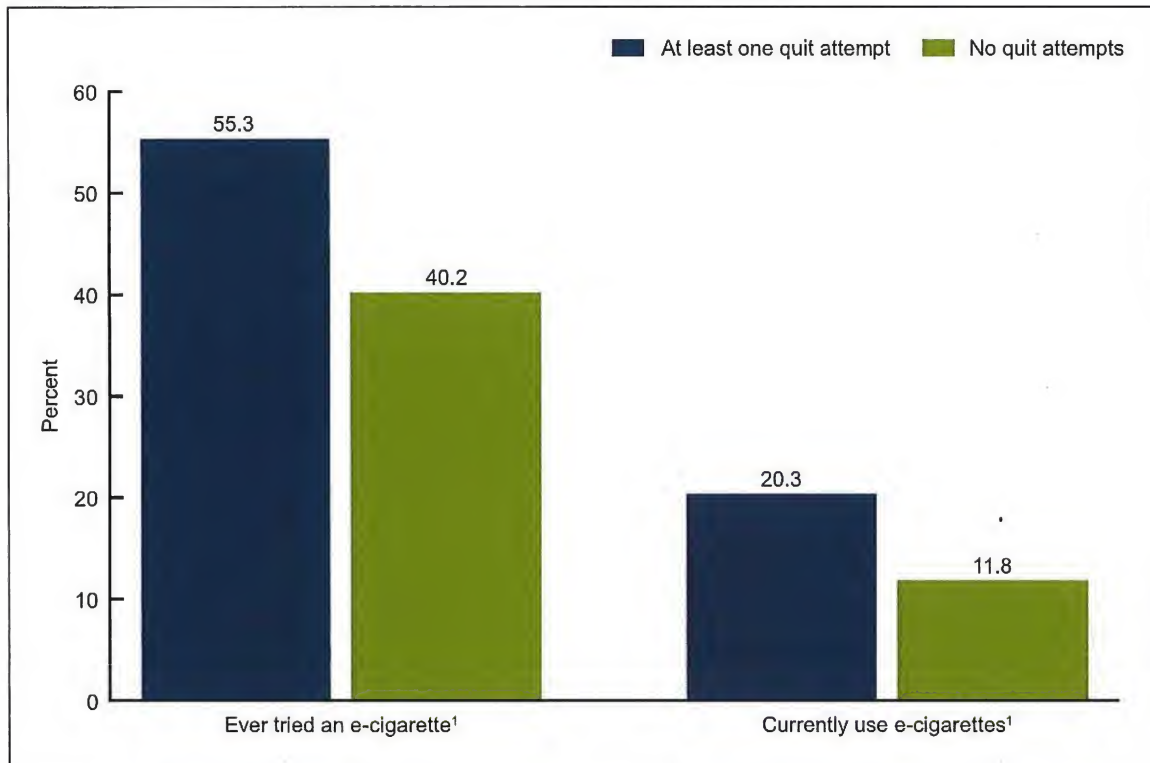
NOTES: Current e-cigarette users have ever tried an e-cigarette, even once, and currently use them every day or some days. Current cigarette smokers have ever smoked 100 cigarettes in their lifetime and currently smoke every day or some days. Based on household interviews with adults aged 18 and over.

SOURCE: CDC/NCHS, National Health Interview Survey, 2014.

Current cigarette smokers who had tried to quit in the past year were more likely to use e-cigarettes than those who had not tried to quit.

- Current cigarette smokers who had tried to quit smoking in the past year were more likely than smokers who had not tried to quit to have ever tried an e-cigarette (Figure 4).
- Current cigarette smokers who had tried to quit in the past year (20.3%) were almost twice as likely as cigarette smokers who had not tried to quit (11.8%) to currently use e-cigarettes.

Figure 4. Percentage of adult current cigarette smokers who had ever tried and percentage who currently use e-cigarettes, by past year cigarette smoking quit attempt status: United States, 2014



¹Percentages are significantly different across quit attempt groups.

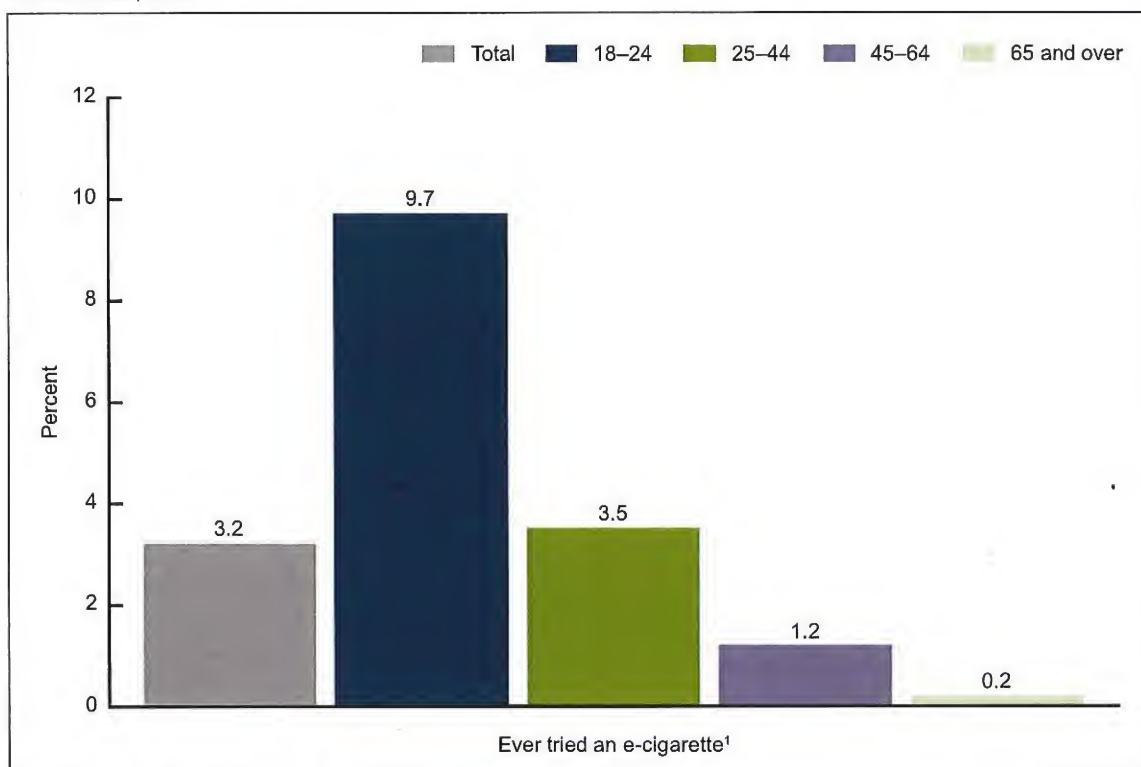
NOTES: Current e-cigarette users have ever tried an e-cigarette and currently use them every day or some days. Information is not available on whether e-cigarettes were used before or after the quit attempt. Based on household interviews with adults aged 18 and over.

SOURCE: CDC/NCHS, National Health Interview Survey, 2014.

Among adults who had never smoked cigarettes, young adults aged 18–24 were more likely than older adults to have tried e-cigarettes.

- Among adults who had never smoked cigarettes, the percentage who had ever tried an e-cigarette, even one time, was highest for those aged 18–24 (9.7%) and declined as age increased (Figure 5).
- Among adults aged 45 and over who had never smoked cigarettes, 1% or less had ever tried an e-cigarette even once.

Figure 5. Percentage of adults who had never smoked cigarettes and who had ever tried an e-cigarette, by age: United States, 2014



¹Significant linear trend for age.

NOTES: Adults who had never smoked cigarettes includes those who had smoked fewer than 100 cigarettes in their lifetime. Based on household interviews with adults aged 18 and over.

SOURCE: CDC/NCHS, National Health Interview Survey, 2014.

Summary

The National Health Interview Survey (NHIS) first began collecting data about e-cigarette use in 2014. The estimates presented in this report provide a foundation for understanding who is using e-cigarettes and for monitoring changes in e-cigarette use among U.S. adults over time.

In 2014, men were more likely than women to have ever tried e-cigarettes but were not more likely to be current users. Younger adults were more likely than older adults to have tried e-cigarettes and to currently use e-cigarettes. Both non-Hispanic AIAN and non-Hispanic white adults were more likely than non-Hispanic black, non-Hispanic Asian, and Hispanic adults to have ever tried e-cigarettes and to be current e-cigarette users.

When examined in the context of conventional cigarette smoking, use of e-cigarettes was highest among current and recent former cigarette smokers, and among current smokers who had made a quit attempt in the past year. Although fewer than 4% of adults who had never smoked conventional cigarettes had ever tried an e-cigarette, nearly 1 in 10 never-smokers aged 18–24 had tried an e-cigarette at least once.

Definitions

Cigarette smoking status: Adults were asked if they had smoked at least 100 cigarettes in their lifetime and, if yes, whether they currently smoked cigarettes every day, some days, or not at all. Those who smoked every day or some days were classified as current smokers. Adults who had not smoked 100 cigarettes were classified as having never smoked. Adults who had smoked 100 cigarettes but were not smoking at the time of interview were asked how long ago they last smoked. Former smokers were then classified as recent former smokers (quit within the past year) or long-term former smokers (quit at least 1 year earlier).

E-cigarette use: Use of e-cigarettes was determined by first describing an e-cigarette for the respondent (“The next questions are about electronic cigarettes, often called e-cigarettes. E-cigarettes look like regular cigarettes, but are battery-powered and produce vapor instead of smoke.”). The respondent was then asked, “Have you ever used an e-cigarette, even one time?” Those who said “yes” were referred to as having “ever tried an e-cigarette.” Adults who had ever used an e-cigarette, even one time, were then asked, “Do you now use e-cigarettes every day, some days, or not at all?” Current e-cigarette use includes respondents who reported using e-cigarettes every day or some days.

Quit attempt: Adults who were current cigarette smokers were asked if they had stopped smoking cigarettes for more than 1 day in the past year because they were trying to quit smoking. Smokers responding “yes” were classified as having made a quit attempt in the past year.

Race and Hispanic or Latino origin: The revised 1997 Office of Management and Budget standards for race (9) were used for the classification of race and Hispanic or Latino origin. A person’s race is described by one or more of five racial groups: white, black or African American, American Indian or Alaska Native, Asian, and Native Hawaiian or Other Pacific Islander. Data on race and Hispanic or Latino origin are collected separately but combined for reporting. Not shown separately are data for Native Hawaiian or Other Pacific Islander, and for persons of two or more races, due to small sample sizes. Persons of Hispanic or Latino origin may be of any race.

Data source and methods

Data from the 2014 NHIS were used for this analysis. NHIS data are collected continuously throughout the year for the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics (NCHS) by interviewers from the U.S. Census Bureau. NHIS includes information about the health characteristics and health care of the civilian noninstitutionalized population of the United States. Questions about lifetime and current e-cigarette use were first asked in NHIS in 2014, in the Sample Adult component ($n = 36,697$). The questions followed a series of questions on use of conventional cigarettes, noncigarette combustible tobacco, and smokeless tobacco products.

Estimates in this report are nationally representative of civilian adults aged 18 and over living in households across the United States. SAS-callable SUDAAN software was used to produce estimates and variances. Differences between percentages were evaluated using two-sided significance tests at the 0.05 level. Estimates with a relative standard error greater than 30% but less than 50% are indicated with an asterisk. Cochran-Mantel-Haenszel tests for trend were used to evaluate trends in e-cigarette use across age groups.

About the authors

Charlotte A. Schoenborn and Renee M. Gindi are with CDC's National Center for Health Statistics, Division of Health Interview Statistics.

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NCHS Data Brief ■ No. 217 ■ October 2015

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Case closed in Fort Plain liquid nicotine death

Police: 18-month-old boy accidentally consumed e-cigarette ingredients

By Keshia Clukey Updated 7:10 am, Monday, April 13, 2015



IMAGE 1 OF 6

Eli James "EJ" Hotaling, 1, of Canajoharie, died Dec. 9 after swallowing liquid nicotine. ORG XMIT: q8OU2IO-xc43GF8FQSoY

Fort Plain

The investigation into the December death of an 18-month-old Montgomery County boy who drank liquid nicotine is finally closed, with Fort Plain police deeming the incident accidental.

Eli James "EJ" Hotaling, who would have turned 2 on May 17, is the first child in the country to die from accidentally swallowing the toxic ingredient in electronic cigarettes, according to the **American Academy of Pediatrics**.

A summary of the police report released by village police Friday provides further details of the events leading up to his death.

On Dec. 9, Eli was being watched by his mother, Brenda Hotaling, and **John Kinard**, who occasionally lived at the home, while his biological mother, Alyssa Hotaling, was Christmas shopping, according to the police summary.

The **Garfield Street** house was in disarray because Brenda Hotaling's sister Belinda was in the process of moving in.

Not knowing that Eli was going to be at the house, **Belinda Hotaling** left an uncapped bottle containing a nicotine solution on a low table in the dining room, police said. She was not home during the incident.

More Information

For a brief moment, Brenda Hotaling and Kinard had their backs turned to look through boxes for a remote control and SpongeBob SquarePants DVD, unaware of the open bottle,

according to the summary.

When they looked back, Eli was holding the opaque brown bottle.

Kinard, immediately thinking Eli had drunk the solution, carried him across the street to the home of now-retired county **Undersheriff Jeff Smith** for help while Brenda Hotaling called 911, according to the report. Eli then began convulsing.

He later was pronounced dead at **Little Falls Hospital**.

According to the coroner's report, Eli died from nicotine ingestion, which caused cardiac arrhythmia.

Liquid nicotine is toxic in doses as small as a half-teaspoon, and even a small

splash of the substance on children's skin can make them very ill, according to the American Academy of Pediatrics.

The bottle Eli consumed contained a mixture of liquid nicotine and diluting liquids, which Belinda Hotaling had bought online and combined to use in her electronic cigarette, according to the police investigation.

It was labelled Heartland Vapes, 100 milligrams, police said. The company, based out of Oklahoma City, is a distributor and manufacturer of eLiquids and ingredients. On the company's website, childproof caps for brown, glass bottles like the one described by police are available for sale separately from the ingredients and containers.

The cap from Belinda Hotaling's bottle was never found, police said. According to the family it was not childproof.

After Eli's death, Gov. **Andrew Cuomo** in December signed a bill requiring child-resistant packaging on all liquid nicotine sold in the state and banning the sale of the lethal substance to those under 18.

Federal legislation mandating childproof packaging was reintroduced on Capitol Hill earlier this year and in February was unanimously approved by the **Senate Commerce Committee**, one step closer to becoming law.

Now that the case is closed, Eli's family plans on filing a lawsuit against Heartland Vapes, Alyssa Hotaling said.

"No amount of money will bring my son back," she said. "I'm hoping it will save some other kid's life."

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Table 17A. Substance Categories Most Frequently Involved in Human Exposures (Top 25).

Substance (Major Generic Category)	All substances	% ^a	Single substance exposures	% ^b
Analgesics	298,633	11.50	193,037	9.90
Cosmetics/personal care products	199,838	7.70	192,940	9.89
Cleaning substances (household)	196,183	7.55	175,594	9.00
Sedative/hypnotics/antipsychotics	153,398	5.91	57,901	2.97
Antidepressants	109,110	4.20	45,123	2.31
Foreign bodies/toys/miscellaneous	103,737	3.99	100,632	5.16
Cardiovascular drugs	101,544	3.91	46,406	2.38
Antihistamines	99,176	3.82	70,682	3.62
Topical preparations	89,287	3.44	87,278	4.47
Pesticides	85,033	3.27	79,405	4.07
Alcohols	70,258	2.71	24,176	1.24
Vitamins	66,206	2.55	56,914	2.92
Cold and cough preparations	65,053	2.51	46,581	2.39
Bites and envenomations	61,857	2.38	61,143	3.13
Stimulants and street drugs	58,514	2.25	33,278	1.71
Antimicrobials	58,514	2.25	48,259	2.47
Hormones and hormone antagonists	56,957	2.19	38,556	1.98
Anticonvulsants	53,102	2.04	21,957	1.13
Gastrointestinal preparations	47,698	1.84	36,180	1.85
Plants	46,376	1.79	43,947	2.25
Dietary supplements/herbals/homeopathic	38,955	1.50	31,254	1.60
Chemicals	38,873	1.50	32,959	1.69
Fumes/gases/vapors	33,973	1.31	31,244	1.60
Hydrocarbons	33,081	1.27	31,031	1.59
Electrolytes and minerals	30,498	1.17	25,089	1.29

^aPercentages are based on the total number of substances reported in all exposures (N = 2,596,915)^bPercentages are based on the total number of single substance exposures (N = 1,950,455)**Table 17B.** Substance Categories with the Greatest Rate of More Serious Exposure Increase (Top 25).

Substance (major generic category)	Increase in more serious exposures per year ^a		More serious exposures in 2013
	Mean	95% CI ^b	
Sedative/hypnotics/antipsychotics	2,559	[2,189, 2,923]	48,482
Analgesics	2,214	[1,953, 2,467]	46,227
Antidepressants	1,164	[1,010, 1,309]	33,924
Cardiovascular drugs	995	[935, 1,048]	19,136
Alcohols	944	[856, 1,031]	21,184
Stimulants and street drugs	650	[269, 1,032]	19,649
Anticonvulsants	608	[560, 656]	13,850
Muscle relaxants	516	[455, 576]	9,310
Antihistamines	493	[418, 567]	12,455
Cold and cough preparations	297	[220, 375]	8,485
Unknown drug	289	[241, 336]	6,123
Hormones and hormone antagonists	255	[236, 273]	5,818
Miscellaneous drugs	112	[73, 151]	2,118
Gastrointestinal preparations	73	[60, 87]	2,585
Diuretics	60	[48, 71]	1,389
Anticoagulants	53	[45, 62]	1,094
Other/unknown nondrug substances	51	[16, 85]	1,125
Vitamins	43	[35, 51]	952
Electrolytes and minerals	42	[33, 50]	965
Anticholinergic drugs	41	[30, 52]	1,117
Antimicrobials	25	[-5, 55]	2,573
Automotive/aircraft/boat products	17	[2, 32]	1,125
Swimming pool/aquarium	11	[-3, 25]	626
Essential oils	11	[9, 12]	227
Cosmetics/personal care products	8	[-3, 20]	2,472

^aMore Serious exposures have medical outcomes of moderate, major or death.^bIncrease and confidence intervals are based on least-squares linear regression of the number of more serious exposures per year for 2000–2013.

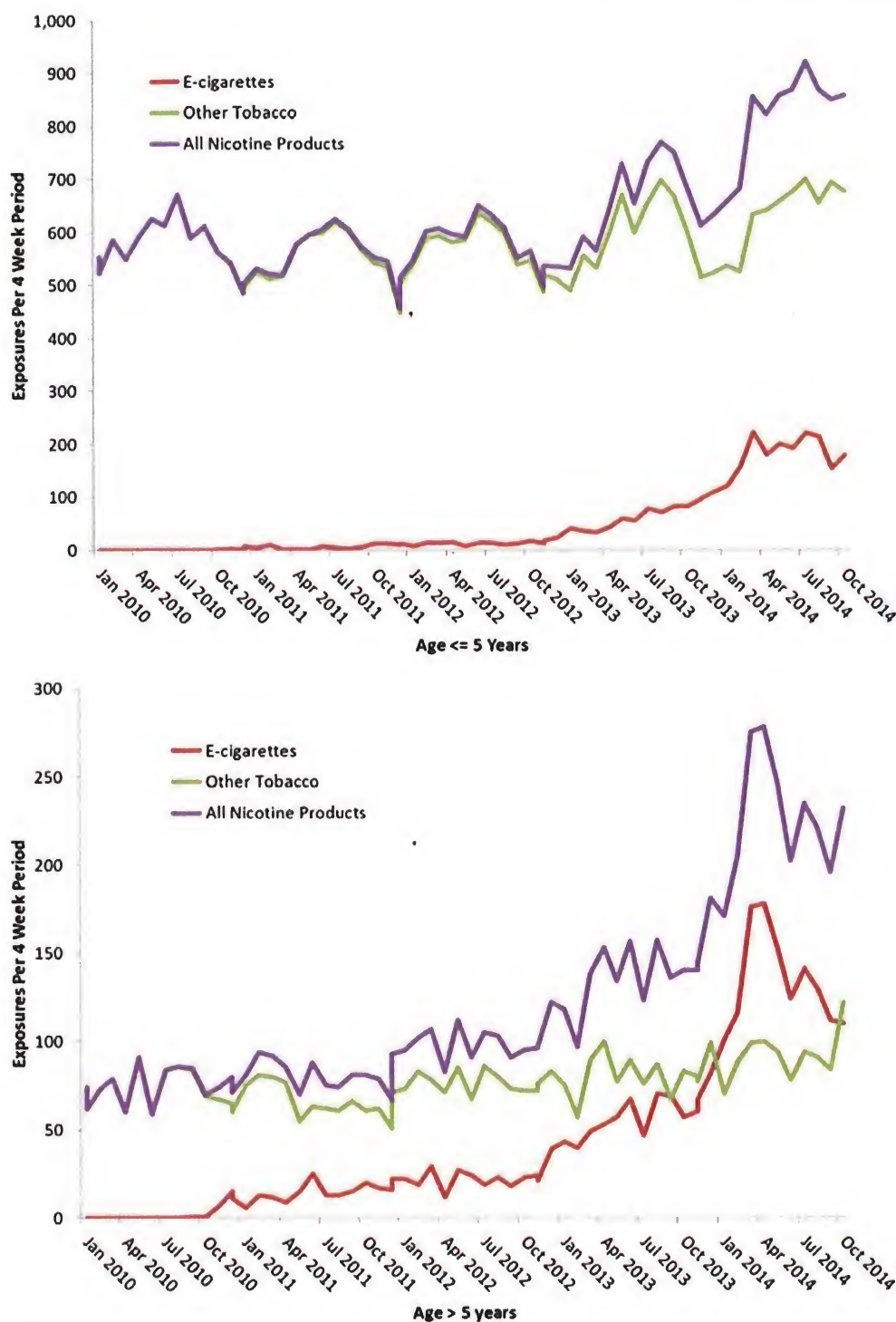


Figure 6. E-cigarette Product Exposures, January 2010–October 2014. The figures show the number of calls received per 4-week period by age group for single-substance human poison exposure calls to an e-cigarette device or refill (— E-cigarette), traditional tobacco products such as cigarettes, snuff, and chewing tobacco (— Other Tobacco) and the sum of the two groups (— All Nicotine Products) since January 2010. Pharmaceutical nicotine products are excluded (colour version of this figure can be found in the online version at www.informahealthcare.com/ctx).

severe morbidity and mortality because of incorrect internet information or no PC management. The net effect could be more severe poisoning outcomes because fewer people took advantage of PC services, with a resultant increased burden on the national health care infrastructure as may be reflected in the increased number of cases managed in a health care facility this year.

NPDS statistical analyses indicate that all analgesic exposures including opioids and sedatives are increasing year over year. This trend is shown in Table 17B and Figure 5. NPDS data mirror CDC data that demonstrates similar findings.⁽¹⁰⁾ Thus, NPDS provides a real-time view of these public health issues without the need for data source extrapolations.



Press release

E-cigarettes around 95% less harmful than tobacco estimates landmark review

From: Public Health England (<https://www.gov.uk/government/organisations/public-health-england>)

First published: 19 August 2015

Part of: Smoking (<https://www.gov.uk/government/policies/smoking>)

Expert independent review concludes that e-cigarettes have potential to help smokers quit.



An expert independent evidence review

(<https://www.gov.uk/government/publications/e-cigarettes-an-evidence-update>) published today by Public Health England (PHE) concludes that e-cigarettes are significantly less harmful to health than tobacco and have the potential to help smokers quit smoking.

Key findings of the review include:

- the current best estimate is that e-cigarettes are around 95% less harmful than smoking
- nearly half the population (44.8%) don't realise e-cigarettes are much less harmful than smoking
- there is no evidence so far that e-cigarettes are acting as a route into smoking for children or non-smokers

The review, commissioned by PHE and led by Professor Ann McNeill (King's College London) and Professor Peter Hajek (Queen Mary University of London), suggests that e-cigarettes may be contributing to falling smoking rates among adults and young people. Following the review PHE has published a paper on the implications of the evidence for policy and practice (<https://www.gov.uk/government/publications/e-cigarettes-an-evidence-update>).

The comprehensive review of the evidence finds that almost all of the 2.6 million adults using e-cigarettes in Great Britain are current or ex-smokers, most of whom are using the devices to help them quit smoking or to prevent them going back to cigarettes. It also provides reassurance that very few adults and young people who have never smoked are becoming regular e-cigarette users (less than 1% in each group).

However, the review raises concerns that increasing numbers of people think e-cigarettes are equally or more harmful than smoking (22.1% in 2015, up from 8.1% in 2013: ASH Smokefree GB survey) or don't know (22.7% in 2015, ASH Smokefree GB survey).

Despite this trend all current evidence finds that e-cigarettes carry a fraction of the risk of smoking.

Emerging evidence suggests some of the highest successful quit rates are now seen among smokers who use an e-cigarette and also receive additional support from their local stop smoking services.

Professor Kevin Fenton, Director of Health and Wellbeing at Public Health England said:

“ Smoking remains England’s number one killer and the best thing a smoker can do is to quit completely, now and forever.

E-cigarettes are not completely risk free but when compared to smoking, evidence shows they carry just a fraction of the harm. The problem is people increasingly think they are at least as harmful and this may be keeping millions of smokers from quitting. Local stop smoking services should look to support e-cigarette users in their journey to quitting completely.”

Professor Ann McNeill, King’s College London and independent author of the review, said:

“ There is no evidence that e-cigarettes are undermining England’s falling smoking rates. Instead the evidence consistently finds that e-cigarettes are another tool for stopping smoking and in my view smokers should try vaping and vapers should stop smoking entirely.

E-cigarettes could be a game changer in public health in particular by reducing the enormous health inequalities caused by smoking.”

Professor Peter Hajek, Queen Mary University London and independent author of the review said:

“ My reading of the evidence is that smokers who switch to vaping remove almost all the risks smoking poses to their health. Smokers differ in their needs and I would advise them not to give up on e-cigarettes if they do not like the first one they try. It may take some experimentation with different products and e-liquids to find the right one.”

Professor Linda Bauld, Cancer Research UK’s expert in cancer prevention, said:

“ Fears that e-cigarettes have made smoking seem normal again or even led to people taking up tobacco smoking are not so far being realised based on the evidence assessed by this important independent review. In fact, the overall evidence points to e-cigarettes actually helping people to give up smoking tobacco.”

“ Free Stop Smoking Services remain the most effective way for people to quit but we recognise the potential benefits for e-cigarettes in helping large numbers of people move away from tobacco.

Cancer Research UK is funding more research to deal with the unanswered questions around these products including the longer-term impact.”

Lisa Surtees, acting director at Fresh Smoke Free North East, the first region where all local stop smoking services are actively promoted as e-cigarette friendly, said:

“ Despite making great strides to reduce smoking, tobacco is still our biggest killer. Our region has always kept an open mind towards using electronic cigarettes as we can see the massive potential health benefits from switching.

All of our local NHS Stop Smoking Services now proactively welcome anyone who wants to use these devices as part of their quit attempt and increase their chance of success.”

Ends

Public Health England press office

Email phe-pressoffice@phe.gov.uk

Telephone 020 7654 8400

Out of hours telephone 020 8200 4400

Please contact PHE press office for:

- the full review E-cigarettes: an evidence update - A report commissioned by Public Health England (<https://www.gov.uk/government/publications/e-cigarettes-an-evidence-update>)
- interviews with PHE spokespeople or the review's independent authors
- case studies of stop smoking services who work with e-cigarette users and smokers who have quit completely with a combination of e-cigarettes and attending a service

Notes to Editors:

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. It does this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. PHE is an operationally autonomous executive agency of the Department of Health. www.gov.uk/phe (<http://www.gov.uk/phe>), Twitter: @PHE_uk (https://twitter.com/PHE_uk), Facebook: www.facebook.com/PublicHealthEngland (<http://www.facebook.com/PublicHealthEngland>)

PHE's remit letter for 2014 to 2015 requested an update of the evidence around e-cigarettes. PHE commissioned Professors Ann McNeill and Peter Hajek to review the available evidence. The review builds on previous evidence summaries published by PHE in 2014.

The full list of authors of the report are:

- McNeill A, Brose LS, Calder R, Hitchman SC: Institute of Psychiatry, Psychology & Neuroscience, National Addiction Centre, King's College London and UK Centre for Tobacco & Alcohol Studies
- Hajek P, McRobbie H (Chapters 9 and 10): Wolfson Institute of Preventive Medicine, Barts and The London School of Medicine and Dentistry Queen Mary, University of London and UK Centre for Tobacco & Alcohol Studies

Implications of the evidence for policy and practice: Based on the findings of the evidence review PHE advises that:

- e-cigarettes have the potential to help smokers quit smoking, and the evidence indicates they carry a fraction of the risk of smoking cigarettes but are not risk free
- e-cigarettes potentially offer a wide reach, low-cost intervention to reduce smoking in more deprived groups in society where smoking is elevated, and we want to see this potential fully realised
- there is an opportunity for e-cigarettes to help tackle the high smoking rates among people with mental health problems, particularly in the context of creating smokefree mental health units
- the potential of e-cigarettes to help improve public health depends on the extent to which they can act as a route out of smoking for the country's eight million tobacco users, without providing a route into smoking for children and non-smokers. Appropriate and proportionate regulation is essential if this goal is to be achieved
- local stop smoking services provide smokers with the best chance of quitting successfully and we want to see them engaging actively with smokers who want to quit with the help of e-cigarettes
- we want to see all health and social care professionals providing accurate advice on the relative risks of smoking and e-cigarette use, and providing effective referral routes into stop smoking services
- the best thing smokers can do for their health is to quit smoking completely and to quit for good. PHE is committed to ensure that smokers have a range of evidence-based, effective tools to help them to quit. We encourage smokers who want to use e-cigarettes as an aid to quit smoking to seek the support of local stop smoking services
- given the potential benefits as quitting aids, PHE looks forward to the arrival on the market of a choice of medicinally regulated products that can be made available to smokers by the NHS on prescription. This will provide assurance on the safety, quality and effectiveness to consumers who want to use these products as quitting aids

- the latest evidence will be considered in the development of the next Tobacco Control Plan for England with a view to maximising the potential of e-cigarettes as a route out of smoking and minimising the risk of their acting as a route into smoking

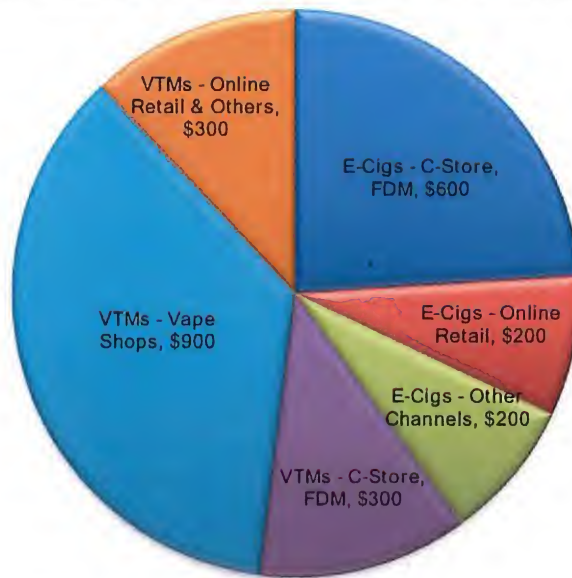
From October this year it will be an offence to sell e-cigarettes to anyone under the age of 18 or to buy e-cigarettes for them. The government is consulting on a comprehensive array of regulations (<https://www.gov.uk/government/consultations/draft-regulations-on-the-sale-and-manufacture-of-tobacco-products>) under the European Tobacco Products Directive.

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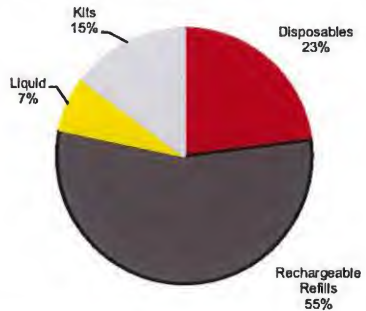
Exhibit 9. 2014 Vapor Market Breakdown – 6 Distinct Market Segments (in \$M)



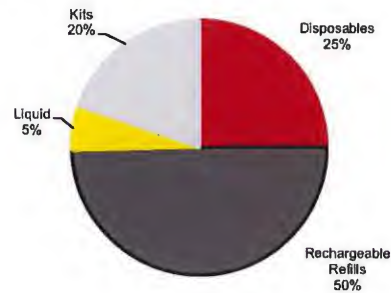
Source: Wells Fargo Securities, LLC estimates

Exhibit 10. Vapor Market Breakdown by Sub-Segment – Per Nielsen E-Cig Category Data

Sales Mix 4-Wk Ending 10/31/15 (\$ Sales \$53.3M)



Sales Mix 52-Wk Ending 10/31/15 (\$ Sales \$796.2M)



Source: Nielsen Total US xAOC Including Convenience Database and Wells Fargo Securities, LLC